

The Agency published a final rule on December 3, 1999, codified in § 203.50(a), that contained certain requirements concerning prescription drug distribution. Specifically, it required that before the wholesale distribution of any prescription drug to another wholesale distributor or retail pharmacy for which the seller is not an authorized distributor of record, the wholesale distributor must provide to the purchaser a statement identifying each prior sale, purchase or trade. Further, it contained a list of specific information to be contained in the identifying statement. As explained previously, this regulation is the subject of a preliminary injunction. In the December 1999 final rule, the Agency estimated that the wholesale distribution requirements, including the drug identifying (or origin) statement and a separate distributor list to be provided by manufacturers, would together impose \$258,000 in annual recordkeeping costs. In making this estimate, the Agency judged that the marginal costs for the inclusion of the additional information that § 203.50(a) would have required beyond that information that would be required in the PDMA pedigree provision would be negligible, and did not increase its cost estimate to reflect this additional effort. The removal of § 203.50(a), therefore, is expected to reduce compliance costs by only that negligible amount that the Agency did not separately estimate for the final rule, as the pedigree provision of the PDMA still requires its own, slightly less expansive, pedigree provision. This regulatory action that removes a provision of the December 1999 final rule is expected to reduce the previously estimated annual compliance costs of \$258,000 for this provision by a negligible, but unquantified, amount.

#### V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VI. Environmental Impact

The Agency has determined under 21 CFR 25.30 this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set

forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### VIII. Proposed Effective Date

The Agency is proposing that any final rule that may issue based upon this proposed rule become effective upon its publication in the **Federal Register**.

#### IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 203 be amended as follows:

#### PART 203—PRESCRIPTION DRUG MARKETING

1. The authority citation for 21 CFR part 203 continues to read as follows:

**Authority:** 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

#### § 203.50 [Amended]

2. Section 203.50 is amended by removing and reserving paragraph (a).

Dated: July 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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#### DEPARTMENT OF STATE

#### 22 CFR Part 123

RIN 1400-AC85

[Public Notice 7524]

#### International Traffic in Arms Regulations: International Import Certificate

**AGENCY:** Department of State.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to remove reference to the International Import Certificate. This amendment will effectively cease the Department's current practice of accepting DSP-53 submissions, as there is no statutory, regulatory, or other authoritative basis for the Department to do so.

**DATES:** The Department of State will accept comments on this proposed rule until August 29, 2011.

#### ADDRESSES:

Interested parties may submit comments within 45 days of the date of the publication by any of the following methods:

- *E-mail:*  
*DDTCResponseTeam@state.gov* with the subject line, "International Import Certificate, ITAR Section 123.4."
- *Internet:* View this notice by searching for its RIN number on the U.S. Government regulations Web site at <http://www.regulations.gov>.

#### FOR FURTHER INFORMATION CONTACT:

Samuel C. Harmon, Office of Defense Trade Controls Policy, Department of State, by *telephone:* (202) 663-2728; *fax:* (202) 261-8199; or *e-mail:* *harmonsc@state.gov*. ATTN: International Import Certificate, ITAR Section 123.4.

**SUPPLEMENTARY INFORMATION:** The Arms Export Control Act authorizes the President to control the import and export of defense articles. Executive Order 11958, as amended, delegated the authority to regulate permanent exports and temporary imports and exports of defense articles to the Department of State, and delegated the authority to regulate permanent imports to the Attorney General. The International Import Certificate (IIC), Form BIS-645P/ATF-4522/DPS-53, is identified as a form issued by the Department of Commerce's Bureau of Industry & Security; the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives; and the Department of State's Directorate of Defense Trade Controls (DDTC). It is meant to

standardize procedures used to facilitate international trade. However, while DDTC typically receives approximately 600 IIC submissions a year, there is no statutory, regulatory, or other authoritative basis for the Department of State to receive submission or pursue enforcement of the IIC. The Department of State's DSP-61 Application/License for Temporary Import of Unclassified Defense Articles and DSP-85 Application/License for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Related Classified Technical Data account for its authority to control temporary imports of defense articles. The Department of State's retention of the IIC is duplicative and unnecessary. Therefore, DDTC proposes to revise § 123.4 to reflect its decision to no longer to accept submissions of the International Import Certificate (DSP-53). DDTC will also make conforming changes to § 120.28 to remove reference to the DSP-53. For temporary import exemptions in which the foreign exporter requires documentation, the U.S. importer will be required to obtain a DSP-61 or a DSP-85. The Bureau of Industry & Security and the Bureau of Alcohol, Tobacco, Firearms and Explosives will continue to adjudicate International Import Certificate submissions for items under their jurisdiction.

### Regulatory Analysis and Notices

#### Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from § 553 (Rulemaking) and § 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this proposed rule is exempt from the rulemaking provisions of the APA, the Department is publishing this proposed rule with a 45-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

#### Regulatory Flexibility Act

Since this proposed amendment is not subject to the notice-and-comment procedures of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

#### Unfunded Mandates Reform Act of 1995

This proposed amendment does not involve a mandate that will result in the

expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### Executive Order 13175

The Department has determined that this proposed rule will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Section 5 of Executive Order 13175 do not apply to this rule.

#### Small Business Regulatory Enforcement Fairness Act of 1996

This proposed amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

#### Executive Orders 12372 and 13132

This proposed amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this proposed amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this proposed amendment.

#### Executive Order 12866

The Department of State does not consider this proposed rule to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review. The Department is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules governing the conduct of this function are exempt from the requirements of Executive Order 12866.

#### Executive Order 13563

The Department of State has considered this proposed rule in light of Section 1(b) of Executive Order 13563, dated January 18, 2011, and affirms that

this regulation is consistent with the guidance therein.

#### Executive Order 12988

The Department of State has reviewed this proposed amendment in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

#### Paperwork Reduction Act

This proposed rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

### List of Subjects in 22 CFR Parts 120 and 123

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, chapter I, subchapter M, parts 120 and 123 are proposed to be amended as follows:

### PART 120—PURPOSE AND DEFINITIONS

1. The authority citation for part 120 continues to read as follows:

**Authority:** Secs. 2, 38, and 71, Public Law 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; E.O. 11958, 42 FR 4311; E.O. 13284, 68 FR 4075; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; Public Law 105-261, 112 Stat. 1920.

2. Section 120.28 is amended by redesignating paragraph (b)(3) as paragraph (c) and by revising paragraph (b)(1) to read as follows:

#### § 120.28 Listing of forms referred to in this subchapter.

\* \* \* \* \*

(b) \* \* \*

(1) International Import Certificate (Form BIS-645P/ATF-4522).

\* \* \* \* \*

### PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

3. The authority citation for part 123 continues to read as follows:

**Authority:** Secs. 2, 38, and 71, Public Law 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105-261, 112 Stat. 1920; Sec 1205(a), Public Law 107-228.

4. Section 123.4 is amended by adding paragraph (c)(4) to read as follows:

#### § 123.4 Temporary import license exemptions.

\* \* \* \* \*

(c) \* \* \*

(4) If the foreign exporter requires documentation for a temporary import

that qualifies for an exemption under this subchapter, the U.S. importer will not be able to claim the exemption and is required to obtain a DSP-61 Application/License for Temporary Import of Unclassified Defense Articles or, for classified defense articles, a DSP-85 Application for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Related Classified Technical Data.

\* \* \* \* \*

Dated: July 6, 2011.

**Ellen O. Tauscher,**

*Under Secretary, Arms Control and International Security, Department of State.*

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## DEPARTMENT OF STATE

### 22 CFR Part 123

**RIN 1400-AC91**

**[Public Notice 7523]**

#### **International Traffic in Arms Regulations: Filing, Retention, and Return of Export Licenses and Filing of Export Information**

**AGENCY:** Department of State.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to reflect changes in the requirements for the return of licenses. Applicants will no longer be required to return certain expired or exhausted DSP-5s. This change will reduce administrative burden on applicants.

**DATES:** *Effective Date:* The Department of State will accept comments on this proposed rule until August 29, 2011.

**ADDRESSES:** Interested parties may submit comments within 45 days of the date of the publication by any of the following methods:

- *E-mail:*

*DDTCResponseTeam@state.gov* with the subject line, "ITAR Amendment—License Return."

- *Internet:* View this notice by searching for its RIN on the U.S. Government regulations Web site at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Nicholas Memos, Office of Defense Trade Controls Policy, Bureau of Political-Military Affairs, Department of State, (202) 663-2804 or FAX (202) 261-8199; E-mail *memosni@state.gov*, Attn: ITAR Amendment—License Return.

**SUPPLEMENTARY INFORMATION:** The Department of State proposes to amend

§ 123.22(c) to institute changes in the requirements for the return of licenses. With this proposed change, applicants with DSP-5 licenses that have been issued electronically by the Directorate of Defense Trade Controls (DDTC) and decremented electronically by the U.S. Customs and Border Protection through the Automated Export System (AES) will no longer need to return them to DDTC. The return of these licenses is redundant and unnecessary as all of the export information has been captured and saved electronically.

All other DSP-5 licenses that do not meet the criteria described above must be returned by the applicant to DDTC. All DSP-61, DSP-73, and DSP-85 licenses, and DSP-94 authorizations, are to be returned by the applicant to DDTC as these licenses and authorizations are not decremented electronically, even if an Electronic Export Information is filed via AES.

Proposed § 123.22(c)(4) provides that licenses issued but not used by the applicant do not need to be returned to DDTC.

Proposed § 123.22(c)(5) provides that licenses which have been revoked by DDTC are considered expired.

Section 123.21(b) is to be amended to conform to the proposed changes to § 123.22(c).

#### **Regulatory Analysis and Notices**

##### *Administrative Procedure Act*

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from § 553 (Rulemaking) and § 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department is publishing this rule with a 45-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

##### *Regulatory Flexibility Act*

Since this amendment is not subject to the notice-and-comment procedures of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

##### *Unfunded Mandates Reform Act of 1995*

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the

private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

##### *Executive Order 13175*

The Department has determined that this rule will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rule.

##### *Small Business Regulatory Enforcement Fairness Act of 1996*

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

##### *Executive Orders 12372 and 13132*

This amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this amendment.

##### *Executive Order 12866*

The Department of State does not consider this rule to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review. The Department is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules governing the conduct of this function are exempt from the requirements of Executive Order 12866.

##### *Executive Order 13563*

The Department of State has considered this rule in light of Executive Order 13563, dated January 18, 2011, and affirms that this regulation is consistent with the guidance therein.

##### *Executive Order 12988*

The Department of State has reviewed the amendment in light of sections 3(a)